K002615

NOV 1 3 2000

Section II - Summary of Safety and Effectiveness

(1) Contact Information

Vincent Cutarelli
Sr. Vice President, Regulatory Affairs and Quality Assurance
Telephone: (949) 595-5424
FAX: (949) 595-4766
Email: vcutarelli@endocare.com

(2) Company Information

Endocare, Inc.
7 Studebaker
Irvine, CA 92618
Telephone: (949) 595-4770
FAX: (949) 595-4766
Web Site: www.endocare.com

(3) Device Name

Endocare CryoCare™ Surgical System with CryoGuide™

(4) Device Description

CryoGuide™ is an accessory to the Endocare CryoCare™ Surgical System. It is designed to be used as a physician training and planning tool for CRYOprobe™ placement during prostate cryoablation procedures. CryoGuide™ is software-controlled and includes a control unit and CRYOprobe™ placement fixture that are designed to be compatible with any ultrasound equipment and ultrasound probe stabilizer currently used for prostate brachytherapy. The control unit consists of a computer and display screen. The computer and display screen are separate components that are not incorporated into the current CryoCare™ Surgical System console.

Using captured ultrasound images, the CryoGuide™ system displays 2-dimensional and 3-dimensional images of the prostate. Suggested placement positions for each CRYOprobe™ are presented based on pre-determined algorithms. During the cryoablation procedure, the physician can display the computer image with the suggested probe positions over the real-time ultrasound image to determine if the probes are being placed in the same location. The placement fixture can be used as a guide to insert the CRYOprobes™ into the prostate. The probes can also be placed without the fixture per

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(5) Indications for Use

The Endocare CryoCare™ Surgical System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate tissue, kidney tissue, liver metastases, tumors, skin lesions and warts. CryoGuide™ is an accessory to the CryoCare™ Surgical System. It is designed to be used as a physician training and planning tool for CryoProbe placement during prostate cryoablation procedures.

The CryoCare™ Surgical System is also indicated for the following uses:

Urology

- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue

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Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

(6) Name of Predicate or Legally Marketed Device

Endocare CryoCare™ Surgical System

(7) Substantial Equivalence

The Endocare CryoCare™ Surgical System with CryoGuide™ is substantially equivalent to the Endocare CryoCare™ Surgical System that was determined to be substantially equivalent on April 10, 1998 (reference K980110). The indications for use are the same for both the new and predicate device. CryoGuide™ is similar in principle to the computer programs and accessories currently utilized for planning radiation therapy of the prostate. However, unlike the brachytherapy systems, CryoGuide™ only provides suggested probe placement and does not calculate treatment parameters (e.g., target freeze cycle). As with the current cryosurgical technique, CRYOprobe™ position and treatment freeze cycles are ultimately determined by the physician using the real-time ultrasound images obtained during the procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vincent Cutarelli
Senior Vice President, Regulatory Affairs
and Quality Assurance
Endocare, Inc.
7 Studebaker
Irvine, California 92618

Re: K002615
Trade Name: Endocare CryoCare™ Surgical System with CryoGuide™
Regulatory Class: II
Product Code: GEH
Dated: August 21, 2000
Received: August 22, 2000

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K002615

Device Name: Endocare CryoCare™ Surgical System with CryoGuide™

Indications for Use: The Endocare CryoCare™ Surgical System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate tissue, kidney tissue, liver metastases, tumors, skin lesions and warts. CryoGuide™ is an accessory to the Endocare CryoCare™ Surgical System. It is designed to be used as a physician training and planning tool for CRYOprobe™ placement during prostate cryoablation procedures.

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Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Concurrence of CDRH, Office of Device Evaluation (ODE):

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002615

Prescription Use: X
(Per 21 CFR 801.109)

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Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

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- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

General Surgery

- Destruction of warts or lesions
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Proctology

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- Ablation of hemorrhoids

Concurrence of CDRH, Office of Device Evaluation (ODE):

Prescription Use: _X_
(Per 21 CFR 801.109)